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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
09/753,008	01/02/2001	Stefan Somlo	96700/658	1280		
75	90 04/14/2004		EXAM	INER		
AMSTER, ROTHSTEIN & EBENSTEIN Attorneys for Applicants			LU, FRANK	LU, FRANK WEI MIN		
90 Park Avenue			ART UNIT PAPER NUMI			
New York, NY	10016		1634			
			DATE MAILED: 04/14/2004	1		

Please find below and/or attached an Office communication concerning this application or proceeding.

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Status

Office Action Summary

Application No.	Applicant(s)	
09/753,008	SOMLO ET AL.	
Examiner	Art Unit	
Frank W Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -- Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
- after SIX (6) MONTHS from the mailing date of this communication.

 If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1)🛛	Responsive to communication(s) filed on <u>24 March 2003</u> .
2a) <u></u> □	This action is FINAL . 2b)⊠ This action is non-final.
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.
Dispositi	on of Claims
4) 🖂	Claim(s) 76-81 is/are pending in the application.
	4a) Of the above claim(s) is/are withdrawn from consideration.
5) 🗌	Claim(s) is/are allowed.
6)🖂	Claim(s) 76-81 is/are rejected.
7)	Claim(s) is/are objected to.
8)[Claim(s) are subject to restriction and/or election requirement.
Applicati	on Papers
9)🖂	The specification is objected to by the Examiner.

Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1.☐ Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No.

10) The drawing(s) filed on <u>02 January 2001</u> is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

* See the attached detailed Office action for a list of the certified copies not received.

o '	Nation	of Dof	erences	Citod	/DTA	9021
11	i Notice	or Kei	erences	Linea	PIO	-897)

-) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>3/24/2003</u>.

4)	Interview Summary (PTO-413)
	Paper Mo/e\/Mail Date

5) Notice of Informal Patent Application (PTO-152)

6) 🔲 Other: _

U.S. Patent and Trademark Office

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DETAILED ACTION

Election/Restrictions

1. In applicant's response to previous restriction, applicant indicates that claims 1-75 has been canceled in the amendment filed on October 24, 2001. After reviewing the restriction made by previous examiner in other art unit and applicant's response filed on March 24, 2003, the examiner agrees to withdraw the restriction made on March 11, 2003. Therefore, claims 76-81 will be examined.

Specification

2. The disclosure is objected to because of the following informalities. (1) applicant indicates that this instant application is a continuation of cases 09/385,752 and 08/651,999 in the first sentence of the specification. However, it is unclear that applicant claims priority for the cases 09/385,752 and 08/651,999 or not; (2) there are Figure 5A to 5G. However, the Brief Description of the Figures only describes Figure 5; and (3) in page 12 of the specification, there are several nucleotide sequences that have more than 10 nucleotides. However, these nucleotide sequences are without SEQ ID Nos.

Appropriate correction is required.

Claim Objections

3. Claims 76 and 79 are objected to because of the following informality: "the PKD2 gene" should be "PKD2 gene".

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4. Claim 79 is objected to because of the following informality: "wherein the mutation comprises one or more deletion, insertion, point, or rearrangement mutations" should be "wherein the mutation comprise deletion, insertion, point, or rearrangement mutation".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

- 5. The following is a quotation of the first paragraph of 35 U.S.C. 112:
 - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 6. Claims 76-81 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for performing the methods recited in claims 76-81 by comparing PKD2 gene in a polynucleotide sample with its wild-type PKD2 gene, does not reasonably provide enablement for the methods recited in claims 76-81 by comparing PKD2 gene from one species in a polynucleotide sample with a wild-type PKD2 gene from other species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands*, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court considered the issue of enablement in molecular biology. The Court summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the

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breadth of the claims. The Court also stated that although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable.

To begin, there is no direction or guidance to perform the methods recited in claims 76-81 by comparing PKD2 gene from one species in a polynucleotide sample with a wild-type PKD2 gene from other species. While the relative skill in the art is very high (the Ph.D. degree with laboratory experience), there is no predictability whether the methods recited in claims 76-81 can be performed by comparing PKD2 gene from one species in a polynucleotide sample with a wild-type PKD2 gene from other species.

Claims 76-81 are directly to a method of detecting the presence or absence of a mutation in the sequence of PKD2. The specification only describes a method of detecting the presence or absence of a mutation in the sequence of PKD2 by comparing human PKD2 gene in a polynucleotide sample with human wild-type gene. However, the specification does not provide guidance for a method of detecting the presence or absence of a mutation in the sequence of PKD2 by comparing PKD2 gene from one species in a polynucleotide sample with a wild-type PKD2 gene from other species. Because the specification does not provide an evidence to show that SEQ ID NO: 6 (human PKD2 with GeneBank Accession No: U50928) is identical among all species, it is unclear whether a method of detecting the presence or absence of a mutation in the sequence of PKD2 can be performed by comparing PKD2 gene from one species in a polynucleotide sample with a wild-type PKD2 gene from other species. In fact, sequence searching shows that SEQ ID NO: 6 (human PKD2) is only partially homologous to murine PKD2 but is not identical to murine PKD2 (see attached results from sequence searching). This suggests that it is impossible to perform the methods recited in claims 76-81 by comparing

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PKD2 gene from one species in a polynucleotide sample with a wild-type PKD2 gene from other species.

With these unpredictable factors, the skilled artisan will have no way to predict the experimental results. Accordingly, it is concluded that undue experimentation is required to make the invention as it is claimed. These undue experimentations at least includes to test whether that the methods recited in claims 76-81 can be performed by comparing PKD2 gene from one species in a polynucleotide sample with a wild-type PKD2 gene from other species.

- 7. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 8. Claims 76-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 9. Claim 76 is rejected as vague and indefinite. Since the step (a) of the claim does not indicate that a polynucleotide sample has PKD2 gene, it is unclear how the difference between the polynucleotide sample and the reference wild-type PKD2 sequence are mutations of PKD 2 gene. Furthermore, the claim does not indicate what gene has "mutations which comprise one or more deletion, insertion, point, or rearrangement mutations". Please clarify.
- 10. Claim 76 is rejected as vague and indefinite. Although the claim is directed to a method of detecting the presence or absence of a mutation in the sequence of PKD2 gene, there is no method step in the claim for Claim 76 is rejected as vague and indefinite and the goal (preamble) can not reach. Please clarify.

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11. Claim 79 is rejected as vague and indefinite. Since the step (a) of the claim does not indicate that a polynucleotide sample has PKD2 gene, it is unclear how performing sequence analysis of the polynucleotide sample can detect the presence or absence of a mutation in the sequence of the PKD2 gene of the subject. Please clarify.

12. Claim 79 recites the limitation "the sequence of the PKD2 gene of the subject" in the claim. There is insufficient antecedent basis for this limitation in the claim because step (a) does not indicate that a subject has a PDK2 gene. Please clarify.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 76-81 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,228,591 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims in this instant application is either anticipated by, or would have been obvious over, the reference claims. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*,

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686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). Although claims 76 and 79 in this instant application are not identical to claim 1 of US Patent No. 6,228,591 B1, claim 1 in US Patent 6,228,591 B1 is directed to the same subject matter and fall entirely within the scope of claims 76 and 79 in this instant application. In other words, claims 76 and 79 in this instant application are anticipated by claim 1 of US Patent No. 6,228,591 B1. Note that claims 77, 78, 80, and 81 are identical to claims 2 and 3 of US Patent No. 6,228,591 B1.

Conclusion

- 15. No claim is allowed.
- 16. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 872-9306 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu **PSA**

April 9, 2004

Page 8



BLASTN 2.2.8 [Jan-05-2004]

Reference:

Altschul, Stephen F., Thomas L. Madden, Alejandro A. Schäffer, Jinghui Zhang, Zheng Zhang, Webb Miller, and David J. Lipman (1997), "Gapped BLAST and PSI-BLAST: a new generation of protein database search programs", Nucleic Acids Res. 25:3389-3402.

RID: 1081784038-16067-188708913800.BLASTQ3

Query=

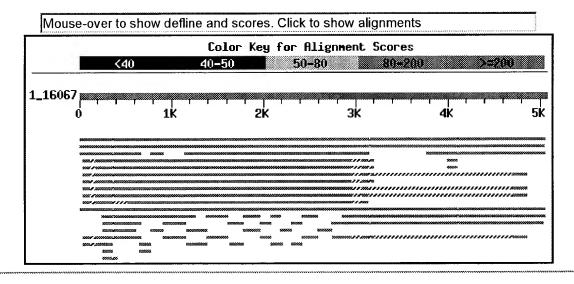
(5073 letters)

Database: All GenBank+EMBL+DDBJ+PDB sequences (but no EST, STS, GSS, or phase 0, 1 or 2 HTGS sequences) 2,226,501 sequences; 10,398,606,914 total letters

If you have any problems or questions with the results of this search please refer to the BLAST FAQs

Taxonomy reports

Distribution of 3819 Blast Hits on the Query Sequence



Sequences producing significant alignments:	Score (bits)	E Value	
gi 33286447 ref NM 000297.2 Homo sapiens polycystic kidney	<u>5453</u>	0.0	
gi 1373168 gb U50928.1 HSU50928 Human autosomal dominant po	<u>5453</u>	0.0	
gi 1477691 gb U56813.1 HSU56813 Human polycystwin mRNA, par	<u> 3895</u>	0.0	

			Games 92022
<pre>gi 38565985 gb BC062969.1 Mus musculus polycystic kidney d</pre>	2319	0.0	
gi 31419361 gb BC053058.1 Mus musculus polycystic kidney d	. <u>2319</u>	0.0	
gi 4150864 emb Y13278.1 MMPOLCYST Mus musculus mRNA for pol	2311	0.0	
gi 26343500 dbj AK053502.1 Mus musculus 0 day neonate eyeb	2311	0.0	
gi 2558834 gb AF014010.1 AF014010 Mus musculus polycystic k	2309	0.0	
gi 31543486 ref NM 008861.2 Mus musculus polycystic kidney	2309	0.0	
gi 34536625 dbj AK128961.1 Mus musculus cDNA fis, clone TR	<u>2165</u>	0.0	
gi 11128446 gb AC084732.1 AC084732 Homo sapiens BAC clone R	<u>1742</u>	0.0	
<u>gi 6855623 gb AF113693.1 AF113693</u> Homo sapiens clone FLB5135	<u>1739</u>	0.0	
gi 3005705 gb AF054992.1 AF054992 Homo sapiens clone 23778	<u>1723</u>	0.0	
gi 3126903 gb AF004873.1 HSPKD15 Homo sapiens autosomal dom	1655	0.0	
gi 4107256 emb Y14120.1 MMY14120 Mus musculus mRNA for poly gi 3126889 gb AF004859.1 HSPKD01 Homo sapiens autosomal dom	$\frac{860}{694}$	0.0	
gi 3126892 gb AF004862.1 HSPKD04 Homo sapiens autosomal dom	502	e-138	
gi 15871680 emb AJ327262.1 HSA327262 Homo sapiens genomic s	464	e-127	
gi 3126894 gb AF004864.1 HSPKD06 Homo sapiens autosomal dom	460	e-125	
gi 3126893 gb AF004863.1 HSPKD05 Homo sapiens autosomal dom	$\frac{450}{201}$	e-122	
gi 15875582 emb AJ331164.1 HSA331164 Homo sapiens genomic s gi 3126896 gb AF004866.1 HSPKD08 Homo sapiens autosomal dom	<u>381</u> 365	e-101 6e-97	
gi 3126896 gb AF004866.1 HSPKD08 Homo sapiens autosomal dom gi 3126895 gb AF004865.1 HSPKD07 Homo sapiens autosomal dom	335	5e-88	
gi 3126901 gb AF004871.1 HSPKD13 Homo sapiens autosomal dom	327	1e-85	
gi 4150862 emb Y14105.1 MMY14105 Mus musculus pkd2 exon 1 a	<u>321</u>	8e-84	
gi 3126902 gb AF004872.1 HSPKD14 Homo sapiens autosomal dom	<u>295</u>	5e-76	88988E
gi 4107461 emb Y14110.1 MMY14110 Mus musculus pkd2 exon 6	278	1e-70	
gi 3126891 gb AF004861.1 HSPKD03 Homo sapiens autosomal dom	<u>266</u>	4e-67	
gi 7531965 gb AF004867.2 HSPKD09 Homo sapiens autosomal dom gi 3126900 gb AF004870.1 HSPKD12 Homo sapiens autosomal dom	$\frac{240}{238}$	2e-59 9e-59	
gi 3126890 gb AF004860.1 HSPKD02 Homo sapiens autosomal dom	230	2e-56	
qi 4107459 emb Y14108.1 MMY14108 Mus musculus pkd2 exon 4	226	3e-55	
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gi 4107463 emb Y14112.1 MMY14112 Mus musculus pkd2 exon 8	<u>198</u>	8e-47	
gi 10121558 gb AF242389.1 AF242389 Mus musculus autosomal d	<u>196</u>	3e-46	
gi 4107458 emb Y14107.1 MMY14107 Mus musculus pkd2 exon 3	$\frac{170}{160}$	2e-38 7e-38	
gi 15872509 emb AJ328091.1 HSA328091 Homo sapiens genomic s	$\frac{168}{161}$	2e-35	
gi 4107468 emb Y14113.1 MMY14113 Mus musculus pkd2 exon 9 gi 15871676 emb AJ327258.1 HSA327258 Homo sapiens genomic s	$\frac{101}{157}$	3e-34	150000H
gi 4107472 emb Y14117.1 MMY14117 Mus musculus pkd2 exon 13	153	4e-33	
gi 4150881 emb Y14111.1 MMY14111 Mus musculus pkd2 exon 7	149	7e-32	
gi 27802045 gb AC011084.17 Homo sapiens chromosome 11, clo	139	6e-29	
gi 4107471 emb Y14116.1 MMY14116 Mus musculus pkd2 exon 12	<u>135</u>	1e-27	
gi 18139513 gb AC069281.6 Homo sapiens BAC clone RP11-44M6	$\frac{133}{131}$	4e-27	
gi 5002592 emb Y17457.1 HOSA17457 Homo sapiens LSFR3A gene,	$\frac{131}{131}$	2e-26 2e-26	
gi 18650683 emb AL445931.29 Human DNA sequence from clone	131	2e-26	
gi 34530661 dbj AK124783.1 Homo sapiens cDNA FLJ42793 fis, qi 12717949 emb AL158207.15 Human DNA sequence from clone	$\frac{131}{131}$	2e-26 2e-26	Girollo
gi 12717949 emb AL158207.15 Human DNA sequence from clone gi 2251212 gb AC002293.1 AC002293 Genomic sequence from Hum	$\frac{131}{131}$	2e-26 2e-26	
gi 2583102 gb AC002102.1 AC002102 Homo sapiens chromosome 9	$\frac{131}{131}$	2e-26	
qi 26096354 dbj AK054397.1 Mus musculus 2 days pregnant ad	131	2e-26	
gi 4107457 emb Y14106.1 MMY14106 Mus musculus pkd2 exon 2	127	2e-25	
gi 19033426 gb AC018450.26 Homo sapiens 3 BAC RP11-80H8 (R	127	2e-25	

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9e-25 🚨 🤨
gi|9408726|emb|AL023803.3|HS616B8 Human DNA sequence from c...
                                                                   125
qi|30522921|qb|AC096537.3| Homo sapiens chromosome 1 clone ...
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gi|23396277|gb|AC124914.3|
                            Homo sapiens chromosome 3 clone ...
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qi|15142005|emb|AL513185.12|
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                             Human DNA sequence from clone ...
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gi|27877146|qb|AC124890.8|
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gi|41324131|gb|AY527817.1| Homo sapiens arachidonate 12-lip...
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qi|21735134|qb|AC079097.6|
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                            Homo sapiens BAC clone RP11-224D...
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qi|15321576|qb|AC079922.5|
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gi|31745092|dbj|AP001028.7|
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gi|3694626|qb|AC005764.1|AC005764
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                                   Homo sapiens chromosome 1...
qi|25136942|emb|AL591845.27| Human DNA sequence from clone ...
                                                                   119
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Alignments

Get selected sequences

Select all

Deselect all

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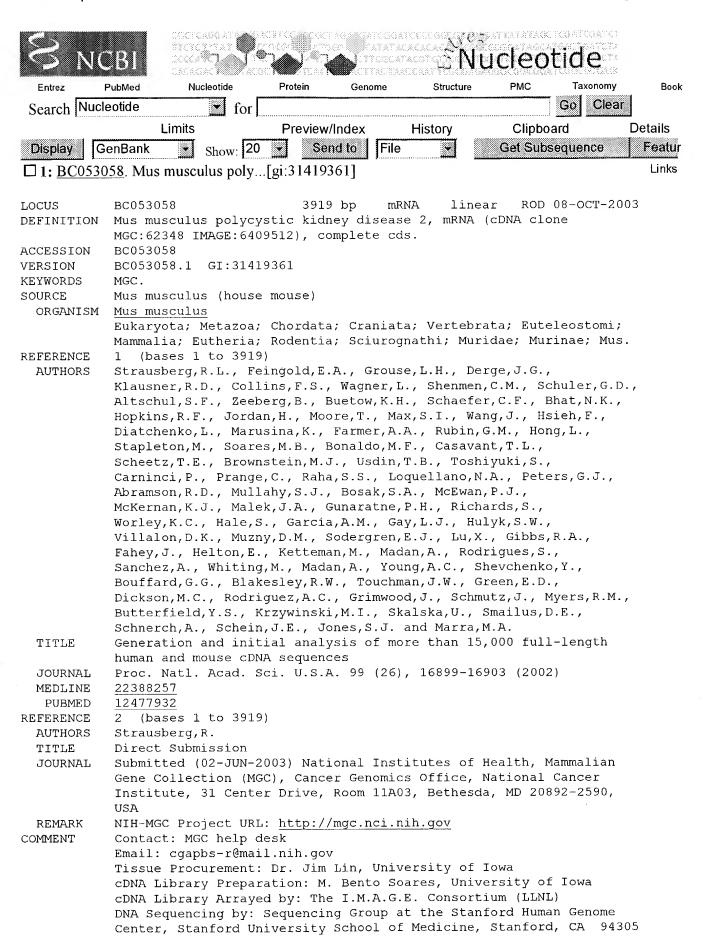
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                            http://www-shgc.stanford.edu
           Contact: (Dickson, Mark) mcd@paxil.stanford.edu
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3841 aacaatttct taactgtaat aatgtgtaca ttacttaata aagacttgac atagtaaaaa
3901 aaaaaaaaaa aaaaaaaaa
```

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Mar 24 2004 12:08:16